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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	18

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,902	GOODMAN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Non-Final Office Action is a reply to the Amendment and Request for Continued Examination under 37 CFR §1.114 of 25 August 2003 (hereinafter, 25 August Paper). Claims 1-12 were previously under consideration. Claims 1 and 9 were amended and claims 13-30 were added in the 25 August Paper. Claims 1-30 are pending and under consideration.

Response to Amendment

Claims 1-12 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record and herein below in the response to arguments.

New grounds for rejection are set forth herein below.

Response to Arguments

Claim Rejections - 35 USC § 112

In response to the rejection of claims 1-12 under 35 U.S.C. § 112, first paragraph, as lacking enablement for gene therapy, Applicant has amended the claims such that they are limited to treating a genetic disease selected from diabetes, heart disease and cancer. First, it must be pointed out that the claims still encompass very broad therapeutic application. Both heart disease and cancer are broad categories of disease, each of which encompass many disparate conditions having distinct etiology. For example, both coronary artery disease and congenital malformations would be encompassed by heart disease, and there are dozens types of cancers which respond to genetic manipulation in different ways. Furthermore, as pointed out in

the previous Office Action, the art teaches that "most diseases are polygenic, involving multiple genetic factors. An example is the case of type 1 diabetes where at least 18 separate chromosomal regions have been associated with genetic susceptibility to the disorder" (page 3).

In the "Remarks", Applicant cites three articles to support enablement of the claimed method as it is now limited to treatment of diabetes, heart disease and cancer. Specifically, Applicant urges that Campbell *et al.* (2000) *Cancer Gene Therapy* 7:1270-1278 demonstrate in mice that adenovirus-mediated $p16^{INK4}$ gene transfer significantly suppressed human breast cancer growth. However, even assuming, *arguendo*, that the teachings of Campbell *et al.* were fully enabling for gene therapy of breast cancer using $p16^{INK4}$ the disclosure is not enabling for the claims because the claims are not limited to gene therapy of breast cancer using $p16^{INK4}$. As Campbell *et al.* points out, the putative therapy is specifically directed to treatment of p16-depleted cells, which is not a uniform feature of all cancers or even all breast cancers (see especially the final paragraph on page 1270). Campbell *et al.* concludes, "the current study suggests that replacement of the wt $p16^{INK4}$ gene may be an effective molecular approach in the treatment of human breast cancers" (page 1277, left column, third full paragraph). Likewise, even the authors of Zang *et al.* (2001) *Int. J. Gynecol. Cancer* 11:18-23, which teaches inhibition of tumor growth in mice bearing an ovarian cancer cell line speculate only that, "this promising procedure could greatly benefit ovarian cancer patients with high expression of HER-2/neu" (abstract). Thus, even if the findings presented by Zhang *et al.* could be further developed to successfully treat ovarian cancer patients with a high expression of HER-2/neu, this is far from enabling for even a small fraction of the diseases encompassed by the term cancer. There is no suggestion in the teachings of Zhang *et al.* or Campbell *et al.*, or in the art of record as a whole,

that cancer gene therapy was generally enabled at the time of filing. Thus, the disclosure fails to provide enablement even for claims limited to cancer.

Applicant urges that Tomiyasu *et al.* teaches, "intra-cardiomuscular transfer of beta2-adrenergic receptor gene in cardomyopathic hamsters significantly elevated stroke volume and cardiac output". However, the improvements shown in cardiac function were small and appeared to be transient (see especially Figure 4). Thus, the findings of Tomiyasu *et al.* cannot be taken as evidence for clinical efficacy of the method disclosed therein in light of the general unpredictability of the gene therapy technology. Furthermore, even if the teachings of Tomiyasu *et al.* were enabling for treatment using the β_2-AR the instant claims are not so limited. Further, Tomiyasu *et al.* conclude, "[improved cardiac function as a result of *in vivo* β_2-AR genetic transduction in an animal model] suggests new possibilities in molecular treatment of severe cardiac failure *in which there are obstacles to the β-AR*" (page 2091, right column; emphasis added). Thus, Tomiyasu *et al.* teach that the therapy contemplated therein would have limited application and the skilled artisan would not expect to be able to use the claimed method to treat heart disease in general.

Next, Applicant again criticizes the age of the articles presented to establish the *prima facie* case of non-enablement. These arguments have been addressed in previous Office Actions.

Applicant asserts that most of the articles submitted in Paper No. 16 show that gene therapy could be used to treat different types of diseases. However, the previous Office Action clearly points out why the vast majority of the art of record fails to provide enablement for gene therapy over any scope. Furthermore, whatever evidence there might be for enabled gene therapy methods is very limited in scope and does not suggest that therapeutic application of promoters

to the treatment of cancer, heart disease and diabetes would be practicable without undue experimentation at the time of filing. Therefore, for reasons of record and herein above, claims 1-12 stand rejected as lacking an enabling disclosure.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not

described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The claims have been amended such that they are now drawn to a method of treating diabetes, heart disease or cancer. Although the disclosure contemplates gene therapy in general, there is no descriptive support for a method of treating diabetes, heart disease or cancer in the originally filed specification or claims. Therefore, claims directed to a method of treating diabetes, heart disease or cancer constitute new matter.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression vector comprising a chimeric regulatory sequence comprising the 900 bp region of the c-myc promoter from -353 to –1257, relative to the transcriptional start site, fused to the first 111 base pairs upstream of the transcription initiation site of the HSP70 promoter and a method of regulating the expression of a nucleic acid in a cell *in vitro*, does not reasonably provide enablement for any promoter comprising at least one exogenous electromagnetic response element or a method of using the enabled promoter *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to maker or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims: The claims are directed to promoter constructs, and methods of using said promoter constructs, capable of regulating expression of heterologous nucleic acids in response to electromagnetic field stimulation, wherein the promoters comprise electromagnetic response elements fused to heterologous regulatory sequences. The specification does not set forth any particular structural limitations on electromagnetic response elements. Therefore, in the broadest embodiments the claims encompass vectors and methods of using vectors comprising any regulatory element capable of responding to electromagnetic fields. More narrow embodiments of the claimed invention limit the electromagnetic response elements as comprising an nCTCTn motif.

Claims 22-30 are directed to a method for regulating expression of a nucleic acid in a cell using the electromagnetic field responsive promoter. According to the broadest reasonable interpretation, the claims encompass a method of regulating expression *in vitro* or *in vivo*. As the specification provides no asserted utility or guidance as to how the skilled artisan is to use the

method *in vivo* other than gene therapy, the claims lack enablement for the method practiced *in vivo* for the reasons set forth in previous Office Actions and herein above.

State of the prior art and level of predictability in the art: With regard to the promoter constructs themselves, the art, like the instant specification, recognizes that a 900 base pair region of the c-myc promoter and a 70 base pair region of the HSP70 promoter are required for electromagnetic field stimulated expression by the native promoters, and that the 900 base pair region from the c-myc promoter can restore the electromagnetic field response when inserted into a HSP70 promoter lacking the endogenous 70 base pair segment required for electromagnetic field stimulation (see, *e.g.*, Blank *et al.* (2001) *J. Cell. Biochem.* 81:689-692). The art further teaches that binding of c-myc to nCTCTn sequences is required for electromagnetic field simulation in the HSP70 promoter (see, *e.g.*, Lin *et al.* (1998) *J. Cell. Biochem.* 69:181-188). However, although the art has identified certain elements that are required for the electromagnetic response in the c-myc or HSP70 promoters, the art does not define the minimal sequence requirements that confer electromagnetic field responsiveness on any promoter. That is, the art does not teach what is sufficient to confer electromagnetic responsiveness such that the skilled artisan would be able to make the full scope of any promoter comprising exogenous electromagnetic response elements and capable of electromagnetic field stimulated expression.

The art generally teaches that the organization of *cis*-regulatory elements in promoters is highly complex and integrated. For example, according to the teachings of Arnone *et al.* (1997) *Development* 124:1851-1864, the 900 base pair region of the c-myc promoter shown to restore the electromagnetic field response to the HSP70 promoter deletion mutant might be considered a

regulatory module. Arnone *et al.* teaches that individual regulatory modules are *always* found to contain multiple transcription factor target sites, and these contribute in various ways to the overall regulatory output (paragraph bridging pages 1851-1852). Arnone *et al.* further teaches that an underestimate of the number of diverse transcription factor interactions found within regulatory modules is approximately 6.2 (first full paragraph on page 1853). Still further, Arnone *et al.* teaches, "[t]here are no examples of regulatory modules serviced only by homeodomain proteins, or Zn finger proteins, and so forth. This suggests diversity in the nature of the protein:protein interactions that are required of the factors in order for each module to generate and communicate its regulatory output" (second full paragraph on page 1853). Thus, Arnone *et al.* teaches that it is highly unlikely that a regulatory module could be defined by the binding of c-myc to the sequence nCTCTn, or that the presence of such a sequence would confer electromagnetic field responsiveness to any promoter.

Lin *et al.* (1998) *J. Cell. Biochem.* 70:297-303 teaches that the complexity of factors participating in the function of expression modules, which Arnone *et al.* teaches is a general feature of these regulatory elements, is likely also found in the electromagnetic field response. Lin *et al.* states, "[b]ased on the magnetic field-induced binding activation of both HSF and AP-1, changes in cell behaviour induced by magnetic fields may well result from a combination of the major stress-responsive transcriptional regulatory pathways. The multiplicity of elements involved in magnetic field-induced HSP70 transcription could result from intersecting and converging signaling pathways" (paragraph bridging the left and right columns on page 299). Furthermore, teachings from the art suggest that the requirements for electromagnetic field responsiveness might not be fully comprised within the 900 base pair segment from the c-myc

promoter. Arnone *et al.* teaches that proximal *cis*-regulatory elements may perform especially important functions in processing the regulatory outputs of more distantly located modules (second full paragraph on page 1856). Lin *et al.* (1999) *J. Cell. Biochem.* 75:170-176 teaches that the HSP70 response to electromagnetic fields involves the trimerization and binding of HSF1 to a heat shock element in the heat shock regulatory domain of the promoter (right column on page 170).

Although the specification states, "[t]he electromagnetic field response elements...can be introduced into any gene promoter not having them" (third paragraph on page 3). The art is silent with regard to what elements comprised within the 900 base pair fragment of the c-myc promoter are sufficient to confer electromagnetic field responsiveness on any promoter not having an electromagnetic field response element, or whether the 900 base pair fragment would provide electromagnetic field responsiveness in any promoter that does not also comprise the heat shock response element of the HSP70 promoter. As the art teaches that *cis*-element regulation of gene expression is complex and unpredictable, the skilled artisan is dependent upon the teachings of the specification to set forth the requirements for an electromagnetic field response element that can be introduced into any promoter not having them such that he can make and use the claimed invention without having to engage in undue experimentation.

Amount of direction provided by the inventor and existence of working examples: The teachings of the instant specification are essentially the same as those available in the art. The working examples provide reduction to practice of a single promoter construct comprising the 900 base pair region required for electromagnetic field response in the c-myc promoter can restore the electromagnetic field response when inserted into a HSP70 promoter lacking the

endogenous 70 base pair segment required for electromagnetic field stimulation. The specification does not teach the minimal requirements for electromagnetic field responsiveness comprised within the 900 base pair fragment of the c-myc promoter, nor does it provide evidence that the 900 base pair fragment would confer electromagnetic field responsiveness on any promoter that does not also comprise the heat shock response element from the HSP70 gene.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, the skilled artisan would not be able to make or use the full scope of the claimed invention without first engaging in undue trial and error experimentation. The disclosure provides a single working example of a promoter having the claim limitations wherein the promoter comprises a 900 base pair module from the c-myc promoter inserted upstream of the HSP70 heat shock responsive element. Applicant claims any vector comprising a promoter wherein the promoter does not comprise an endogenous electromagnetic response element and wherein the promoter comprises at least one exogenous response element which regulates expression of the nucleic acid by application of an electromagnetic field. Given the very limited working examples and the complexity of *cis*-element regulation of gene expression, one of ordinary skill would not know how to make an electromagnetic field response element capable of providing electromagnetic field responsiveness when introduced into any gene promoter not having one. Therefore, the skilled artisan would have to engage in undue trial and error experimentation to construct a promoter element capable of providing electromagnetic field responsiveness regardless of the surrounding promoter structure.

Furthermore, given that there is no evidence that the 900 base pair myc promoter sequence is operative in any context other than within the c-myc gene or in conjunction with the HSP70 heat shock response element and there is no basis upon which one can predict in which heterologous promoters the 900 base pair fragment would be operative, the skilled artisan would have to engage in undue experimentation to construct and test the 900 base pair fragment with every gene promoter not having an electromagnetic response element to identify those which fall within the scope of the claims. For these reasons, making and using any promoter beyond the scope of comprising the 900 bp region of the c-myc promoter from -353 to –1257, relative to the transcriptional start site, fused to the first 111 base pairs upstream of the transcription initiation site of the HSP70 promoter would require undue experimentation.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

As describe above, the claims are directed to promoter constructs, and methods of using said promoter constructs, capable of regulating expression of heterologous nucleic acids in response to electromagnetic field stimulation, wherein the promoters comprise electromagnetic response elements fused to heterologous regulatory sequences. The specification does not set forth any particular structural limitations on electromagnetic response elements. Therefore, in the broadest embodiments the claims encompass vectors and methods of using vectors comprising any regulatory element capable of responding to electromagnetic fields. More narrow embodiments of the claimed invention limit the electromagnetic response elements as comprising an nCTCTn motif.

The Guidelines for Written Description state: "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus" (Federal Register, Vol. 66, No. 4, Column 3, page 1106). "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus" (MPEP §2163(3)(a)(ii)).

The specification provides detailed description of a single species of the promoter of the claimed invention (i.e., a promoter comprising the 900 base pair region from the c-myc promoter inserted into a HSP70 promoter lacking the endogenous 70 base pair segment required for electromagnetic field stimulation). With regard to identifying characteristics, the specification

teaches that binding of c-myc to nCTCTn sequences is required for electromagnetic field simulation in the HSP70 promoter and that a 70 base pair region of the HSP70 promoter and a 900 base pair region of the c-myc promoter are required for electromagnetic field stimulated expression by the native promoters (*Id.*). The specification does not, however, set forth the elements comprised within a promoter capable of providing electromagnetic field responsiveness to any promoter not having an electromagnetic field response element. Therefore, the skilled artisan could not possibly envision the full scope of the claimed subject matter based on the teachings of the specification and would not have recognized the that Applicant was in possession of the full scope of the claimed invention at the time of filing.

Although the specification describes an assay by which the skilled might identify the elements comprised by the claimed promoter, an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property (i.e., it is an electromagnetic response element) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to

the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of any promoter comprising at least one exogenous electromagnetic response element wherein the promoter is regulated by application of an electromagnetic field. Therefore, only the described promoter comprising the 900 bp region of the c-myc promoter from -353 to –1257, relative to the transcriptional start site, fused to the first 111 base pairs upstream of the transcription initiation site of the HSP70 promoter meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of "the step" in line 1. The claims are directed to products and therefore do not comprise steps. Thus the term lacks antecedent basis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER